**SMG 1281.1**

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Office of the Chief Scientist**

**National Center for Toxicological Research**

**Office of the Center Director**

Effective Date: December 14, 2018

## 1. Office of the Center Director (DCPFA).

A. Directs overall Center activities, coordinates and establishes Center policy in the areas of research, management, scientific evaluation, compliance and surveillance.

B. Provides leadership and direction to assure the efficient and effective planning, performance, and evaluation of Center activities.

C. Staffs and supports the operation of the Center's Science Advisory Board to evaluate the relevance and direction of the Center's research programs.

D. Advises and assists top Food and Drug Administration (FDA) management on research strategies that have impact on the development and execution of long-range program goals of the FDA.

E. Provides Executive Secretariat support for the Immediate Office of the Director. Provides central control for and processes all Center public correspondence directed to the Director, including incoming/outgoing correspondence requiring Center policy review, report documents from the Government Accounting Office, Office of Technology Assessment, the Federal Register, etc., and Center-prepared responses to executive communications of interest to the Center Director.

F. Develops, prepares and coordinates the Center's responses to requests for information through the Freedom of Information Act.

G. Supports FDA public and consumer affairs initiatives, including supporting the efforts of the National Center for Toxicological Research (NCTR). Establishes

and coordinates industry/producer group outreach initiatives. Responds to inquiries to the Center from consumers, industry representatives, government officials, health professionals and academics.

H. Maintains the physical and personnel security program for the Center to ensure the protection of NCTR's personnel, equipment, and physical plant; as well as employee's background investigations and suitability requirements in accordance with the provisions of Executive Order 10450 and the Code of Federal Regulations, parts 731, 732, and 736.

I. Maintains NCTR records (research and administrative) in accordance with Department of Health and Human Services (HHS), FDA, and National Archives and Records Administration regulations.

J. Assures compliance with local, state and federal regulations including those promulgated by the Occupational Safety and Health Administration, Environmental Protection Agency, and the Nuclear Regulatory Commission. Ensures Center's compliance with Executive Orders, HHS and FDA regulations, policies and guidelines.

K. Executes/Administers quality assurance programs to ensure compliance with FDA Good Laboratory Practice regulations and HHS Human Subjects Research regulations.

L. Identifies and evaluates all risks with the potential to adversely impact the NCTR in the areas of physical security and regulatory compliance, and develops measures to control, reduce, or eliminate those risks. Risks would also include natural disasters, workplace accidents or illnesses, toxic or hazardous materials spills, or waste, fraud or abuse of resources.

M. Establishes and manages a program to maintain the highest level of quality and integrity for all Center laboratory studies and ensures that all laboratories are in compliance with Good Laboratory Practice Regulations.

**2. Authority and Effective Date.**

The functional statements for the Office of the Center Director were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services**
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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Chief Scientist, National Center for Toxicological Research, Office of the Center Director organization structure depicting all the organizational structures reporting to the Center Director:

Office of the Center Director (DCPFA)

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